

CLAIMS

1. A pharmaceutical composition which is stable and suitable for oral administration to a patient, comprising a mixture of omeprazole and a pharmaceutically acceptable carrier, said carrier comprising at least one water insoluble polymer.
2. The composition of claim 1 wherein said polymer has vinylpyrrolidone units.
3. The composition of claim 2 wherein said polymer is cross-linked polyvinylpyrrolidone.
4. The composition of claim 1 wherein said carrier further comprises water soluble polymers.
5. The composition of claim 4 wherein said polymer is polyvinyl pyrrolidone or vinylpyrrolidone-vinyl acetate copolymer.
6. The composition of claim 1 wherein said carrier comprises at least about 40% by weight of omeprazole.
7. The composition of claim 1 wherein said mixture further comprises other pharmaceutically acceptable excipients.
8. The composition of claim 8 wherein said mixture further comprises a fatty acid glyceride.
9. The composition of claim 8 wherein said mixture further comprises lubricants, plasticizers, fillers and binders.

Q 7

10. The composition of claim 10 wherein the lubricants are selected from the group consisting of talc, magnesium stearate, calcium stearate, polyethylene glycol, sodium stearyl fumarate, and mixtures thereof.
11. The composition of claim 10 wherein the plasticizers are selected from the group consisting of triethyl citrate, polyethylene glycol, and mixtures thereof.
12. The composition of claim 10 wherein the binder is selected from the group consisting of polyvinyl pyrrolidone, starch, low viscosity grade hydroxypropyl methylcellulose, hydroxymethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, and mixtures thereof.
13. The composition of claim 10 wherein the fillers are selected from the group consisting of lactose, sucrose, mannitol, and microcrystalline cellulose.
14. The composition of claim 1 in the form of a capsule, said mixture being contained within a capsule shell made from an enteric material.
15. The composition of claim 14 wherein said mixture contained within said capsule shell is in the form of a powder blend.
16. The composition of claim 14 wherein said mixture contained within said capsule shell is in the form of granules.
17. The composition of claim 1 in the form of a capsule, said mixture being contained within a capsule shell which is coated with an enteric material.

100001-00000000000000000000000000000000

18. The composition of claim 17 wherein said mixture contained within said capsule shell is in the form of a powder blend.
19. The composition of claim 17 wherein said mixture contained within said capsule shell is in the form of granules.
20. The composition of claim 1 in the form of a tablet.
21. The composition of claim 1 in the form of a bead or a pellet, wherein said mixture is coated on a neutral core.
22. The composition of claim 21, wherein said neutral core has previously been coated with a coating mixture before coating with said mixture of claim 1.
23. The composition of claim 22 wherein said coating mixture may contain water soluble or water insoluble polymers optionally with other pharmaceutically acceptable excipients.
24. The composition of claim 21 wherein neutral core coated with said mixture is further coated with one or more intermediate layers, and an outer enteric layer.
25. The composition of claim 24 wherein an enteric layer has an enteric polymer.
26. The composition of claim 24 wherein the intermediate layer(s) may contain water soluble or water insoluble polymers, optionally with other pharmaceutically acceptable excipients.

TOP SECRET - 592562550

- TOP SECRET // EYES ONLY
27. A pharmaceutical composition which is stable and suitable for oral administration to a patient, comprising (a) a neutral core coated with a mixture of omeprazole and a pharmaceutically acceptable carrier, said carrier comprising at least one water insoluble polymer, (b) one or more intermediate layer(s), optionally comprising water soluble or insoluble polymers, and (c) an enteric coated layer.
 28. The composition of claim 27 in the form of a bead or a pellet.
 29. The composition of claim 28 wherein the beads or pellets are compressed into tablets or filled in a capsule.
 30. A process for preparing a stable pharmaceutical composition which is suitable for oral administration, comprising mixing omeprazole together with a pharmaceutically acceptable carrier, said carrier comprising at least one water insoluble polymer.
 31. The process of claim 30 wherein said polymer has vinylpyrrolidone units.
 32. The process of claim 31 wherein said polymer is cross-linked polyvinylpyrrolidone.
 33. The process of claim 30 wherein said carrier further comprises water soluble polymers.
 34. The process of claim 33 wherein said polymer is polyvinyl pyrrolidone or vinylpyrrolidone-vinylacetate copolymer.

35. The process of claim 30 further comprising mixing at least one pharmaceutically acceptable excipient into said mixture.
36. The process of claim 35 wherein said pharmaceutically acceptable excipient is a fatty acid glyceride.
37. The process of claim 35 wherein said pharmaceutically acceptable excipient is a lubricant, plasticizer, filler, or a binder.
38. The process of claim 30 further comprising filling said mixture in the form of a powder blend into a capsule made from an enteric material.
39. The process of claim 30 further comprising coating a capsule shell with an enteric material, and filling said mixture in the form of a powder blend into said capsule shell.
40. The process of claim 30 further comprising granulating said mixture to produce granules, and filling said granules into a capsule shell made from an enteric material.
41. The process of claim 30 further comprising granulating said mixture so as to form granules, coating a capsule shell with an enteric material, and filling said granules into said capsule shell.
42. The process of claim 30 further comprising compressing said mixture into tablets.
43. The process of claim 30 comprising coating said mixture on a neutral core.

09025254567890

44. The process of claim 31 wherein said neutral core has previously been coated before coating of said mixture.
 45. The process of claim 30 wherein neutral core coated with said mixture is further coated with one or more intermediate layers, and an outer enteric layer.
 46. The process of claim 30 further comprising forming beads or pellets.
 47. The process of claim 46 further comprising compressing beads or pellets into tablets or filling said beads or pellets in a capsule.